UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,456	01/26/2004	John C. Kennell	SLU02-010	8365

33436 7590 08/14/2006

SAINT LOUIS UNIVERSITY
OFFICE OF INNOVATION AND INTELLECTUAL PROPERTY
3556 CAROLINE MALL
SUITE C208
ST. LOUIS, MO 63104

EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,456	KENNELL, JOHN C.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 8-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 8-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Applicant's election without traverse of Group I, claims 1-4, 6 and 8-16 in the reply filed on 5/10/06 is acknowledged. SEQ ID NOs 2 and 4-6 are withdrawn from consideration as being directed to non-elected inventions. Non-elected claims have been cancelled in the amendment filed 5/10/06.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Walther et al.

Applicant claims an isolated polynucleotide that comprises a sequence that encodes a reverse transcriptase polypeptide or a fragment of a reverse transcriptase polypeptide, wherein the reverse transcriptase polypeptide comprises a sequence having 88% identity (or at least 88% identity) to SEQ ID NO:1 (pFOXC2) and wherein the polynucleotide comprises (or consists essentially of) a sequence set forth in SEQ ID NO:3 as well as a cell containing said isolated polynucleotide. It is noted that the language "polynucleotide comprises a sequence set forth in SEQ ID NO:3" reads on a polynucleotide containing any sequence of 2 or more nucleotides (i.e. GC or AT, etc.) of SEQ ID NO:3.

Walther et al. (cited by applicant, Mol. Cell, 1999, Vol. 4, pp. 229-238, see whole article, particularly the Abstract, pp. 230, 234, 236) recites polynucleotides encoding pFOXC2 and pFOXC3 and fungal cells containing pFOXC2 and pFOXC3. Applicant, in the instant specification (see p. 13) indicates that pFOXC3 is 88% identical to pFOXC2. Therefore, Walther et al. teaches a polynucleotide that encodes a reverse transcriptase polypeptide comprising a sequence having 88% identity to pFOXC2 (SEQ ID NO:1).

With regard to the "consists essentially of" language in claim 6, the application does not disclose a clear indication of what the basic and novel characteristics actually are, and hence "consisting essentially of" will be construed as equivalent to "comprising." (see MPEP 2111.03).

With regard to the "88% identity" limitation, since the parameters used to calculate the % identity are not recited in the claim, the 88% identity can be calculated using any parameters.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walther et al. in view of Sutherland et al.

Applicant claims an isolated polynucleotide that comprises a sequence that encodes a reverse transcriptase polypeptide or a fragment of a reverse transcriptase polypeptide, wherein the reverse transcriptase polypeptide comprises a sequence having 88% identity to SEQ ID NO:1 (pFOXC2) and wherein the polynucleotide utilizes a universal genetic code.

Walther et al. is applied as in the above 35 USC 102(b) rejection. Walther et al. does not recite that the polynucleotide utilizes a universal genetic code. Walther et al. notes that the pFOXC plasmids are translated using the fungal mitochondrial genetic code.

Sutherland et al. (BioTechniques, 1995, Vol. 18, No. 3, pp. 458-464, see whole article, particularly p. 458, 463-464) recites the procedures used for the conversion of genes using a non-universal (mitochondrial) genetic code to a universal genetic code and the desirability of doing so.

The ordinary skilled artisan, seeking to express the mitochondrial reverse transcriptase disclosed by Walther et al., would have been motivated to alter the polynucleotide encoding said reverse transcriptase to utilize a universal genetic code

because this facilitates the expression of the gene in conventional expression systems which utilize a universal genetic code, as taught by Sutherland et al. It would have been obvious for the ordinary skilled artisan to alter the sequence encoding the claimed fungal mitochondrial reverse transcriptase (taught by Walther et al.) so as to utilize a universal genetic code because Sutherland et al. teaches that the translational machinery maintained in the mitochondria employs a different genetic code that varies from the universal genetic code and that "code-correction" is necessary in order to express mitochondrial genes in conventional expression systems. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 8-10, 12-13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walther et al. in view of Sutherland et al. and Weis et al.

Applicant claims a recombinant vector comprising SEQ ID NO:3 (utilizing a universal genetic code) wherein said sequence is under control of a heterologous promoter (such as the *lac* promoter), *E. coli* cells containing the vector and a method for making the reverse transcriptase of SEQ ID NO:3 comprising expressing the polynucleotide and isolating the protein from the system.

Walther et al. and Sutherland et al. are applied as in the above 35 USC 102(b) and 103(a) rejections. Neither Walther et al. nor Sutherland et al. teach recombinant vectors comprising SEQ ID NO:3 operably linked to a heterologous promoter, cells

containing said vector and a method of making the reverse transcriptase encoded by SEQ ID NO:3.

Weis et al. (US 4,663,290, issued 5/5/87, see whole document, particularly Claims 1-5, columns 9-10, 19-20) recites the desirability of expressing reverse transcriptases in bacterial cells (*E. coli*) using recombinant vectors comprising the reverse transcriptase gene under control of a heterologous promoter.

The ordinary skilled artisan, seeking to express the fungal reverse transcriptase gene (in pFOXC2) disclosed by Walther et al. would have been motivated to code-correct the sequence to a universal genetic code as taught by Sutherland et al. because this is necessary to express the gene in conventional expression systems (such as in *E. coli* or most eukaryotic cells) and clone the sequence into a recombinant expression vector such as that disclosed by Weis et al. because Weis et al. teaches that expression of the reverse transcriptase, and purification of the resulting reverse transcriptase protein (for further analysis of the protein or preparation of cDNAs), can be facilitated by expression of the gene in E. coli cells wherein the gene is under control of a heterologous promoter such as the *lac* promoter. It would have been obvious to code-correct the fungal mitochondrial reverse transcriptase sequence because Sutherland et al. teaches that this is necessary for proper expression of the gene in conventional expression systems and it would have been obvious to express the reverse transcriptase gene (SEQ ID NO:3) in the context of a conventional recombinant expression vector in a cell such as *E. coli* because this is a conventional expression system as recited by Weis et al. and can be used to express reverse transcriptases.

Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 8-10 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walther et al. in view of Sutherland et al., Weis et al. and Morin et al.

Applicant claims a recombinant vector comprising SEQ ID NO:3 (utilizing a universal genetic code) wherein said sequence is under control of a heterologous promoter (such as the *lac* promoter), *E. coli* cells or *Saccharomyces cerevisiae* containing the vector and a method for making the reverse transcriptase of SEQ ID NO:3 comprising expressing the polynucleotide and isolating the protein from the system.

Walther et al., Sutherland et al. and Weis et al. are applied as above. These references do not teach *S. cerevisiae* as a host for the claimed fungal mitochondrial reverse transcriptase (SEQ ID NO:3) or use of heterologous promoters such as the CMV or alcohol dehydrogenase gene promoter or heat shock promoter or tetracycline inducible promoter, etc.).

Morin et al. (US 6,767,719, issued 7/27/04, filed 3/16/98, see whole document, particularly columns 26, 28, 75-76) teaches recombinant vectors comprising genes encoding reverse transcriptase proteins and that they can be transformed into bacterial or yeast cells (specifically *S. cerevisiae* cells) wherein the reverse transcriptase gene is

operably linked to a heterologous promoter such as the CMV promoter, yeast alcohol dehydrogenase gene promoter or heat shock promoter or tetracycline inducible promoter, etc.

The ordinary skilled artisan, seeking to express the fungal reverse transcriptase gene (in pFOXC2) disclosed by Walther et al. would have been motivated to code-correct the sequence to a universal genetic code as taught by Sutherland et al. because this is necessary to express the gene in conventional expression systems (such as in *E. coli* or most eukaryotic cells) and clone the sequence into a recombinant expression vector such as that disclosed by Weis et al. or Morin et al. because Weis et al. and Morin et al. teach that expression of the reverse transcriptase, and purification of the resulting reverse transcriptase protein, can be facilitated by expression of the gene in E. coli cells or S. cerevisiae cells wherein the gene is under control of a heterologous promoter such as the *lac* promoter, CMV promoter, alcohol dehydrogenase promoter, etc.. It would have been obvious to code-correct the fungal mitochondrial reverse transcriptase sequence because Sutherland et al. teaches that this is necessary for proper expression of the gene in conventional expression systems and it would have been obvious to express the reverse transcriptase gene (SEQ ID NO:3) in the context of a conventional recombinant expression vector in a cell such as *E. coli or S. cerevisiae* because these are conventional expression systems as recited by Weis et al. and Morin et al. and can be used to express reverse transcriptases. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant

invention was made, it must be considered that the ordinary skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 11-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims an isolated polynucleotide that comprises a sequence that encodes a reverse transcriptase polypeptide or a fragment of a reverse transcriptase polypeptide, wherein the reverse transcriptase polypeptide comprises a sequence having 88% identity (or at least 88% identity) to SEQ ID NO:1 (pFOXC2) and cells containing said sequences. The claims read on a genus of polynucleotides encoding reverse transcriptases (RTs) or specifically pFOXC-RTs. Applicant discloses two sequences from *Fusarium oxysporum* encoding mitochondrial reverse transcriptases (pFOXC-RTs).

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or

chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention. In the instant case, applicant indicates that the pFOXC-RTs possess unique activities compared with related retroplasmid RTs. However, applicant does not disclose a function-structure relationship with regard to the specific structural motifs in the pFOXC-RTs which impart upon said molecules the unique functional characteristics of pFOXC-RTs. Without knowledge of the structure-function relationships, the skilled artisan would be unable to describe the sequences of RTs with the required % identity, i.e. what nucleotides or residues could be altered with preservation of the activity of the molecule as a RT, or specifically, a pFOXC-RT. It must be considered that the disclosure of two species would not represent a representative number sufficient to describe the entire claimed genus (reading on millions of different molecules). The skilled artisan would not therefore conclude that applicant, at the time of the invention, was in possession of the claimed genus.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Sequences appearing in Figures 4, 7 and 8

have not been identified by appropriate SEQ ID NO identifiers. Any response to this Office Action which does not include compliance with the Sequence Rules will be considered non-responsive.

It is noted that claims 8-16 do not have status identifiers. Any future amendments to the claims which do not include appropriate status identifiers for all claims will be considered non-responsive.

Claims 1, 3, 8, 11 and 15 are objected to as containing non-elected subject matter (SEQ ID NO:s 2 and 4-6). Applicant is required to cancel the non-elected subject matter.

Claim 10 is objected to because of the following informalities: In line 3, after the term "lactose-inducible", the following word should be "promoter"; however, it is misspelled as "promotes". Appropriate correction is required.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
July 20, 2006

DAVID GUZO
PRIMARY EXAMINER